



State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary

December 20, 2005

Docket No. 2002N-0273
Division of Dockets Management [HFA-305]
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

The Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) monitors the health of Wisconsin's domestic animals, regulates animal imports and movements to prevent the spread of disease; licenses animal markets, dealers, and truckers to protect animal health and control diseases. DATCP investigates animal disease outbreaks to determine the nature, source and spread of the disease. The department also licenses manufacturers and distributors of animal feed, assuring that animal feed (including pet food) is unadulterated, or is not misbranded. Compliance with our feed regulations is done through product sampling and facility inspections. DATCP food and meat inspectors regularly inspect processing facilities and sample food and meat products.

DATCP agrees with FDA on the need for the rule change; to further strengthen existing safeguards designed to help prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. We also appreciate how FDA has considered input from our agency and other groups nationwide through previous rulemaking.

DATCP supports the removal from the animal food and feed chain of the cattle origin materials specified in the proposal. Many of Wisconsin feed manufacturers voluntarily discontinued use of animal protein products in ruminant feed prior to the ban in 1997. Our feed industry is so closely connected to our dairy and livestock industries that manufacturers have readily complied with the regulations because the risk of jeopardizing our dairy and livestock industries is too great. However, DATCP has several concerns about the impact of the proposed rule change on our state rendering and meat processing establishments.

Wisconsin has 16 licensed dead animal collectors. These businesses collect dead animals from the producer's premises and deliver them to either an animal food processing plant or a rendering plant. Wisconsin also has over 100 state-inspected meat slaughtering operations and 60 custom meat establishments that will have to remove the brain and spinal cord from the cattle that they process. All establishments will be required to segregate brains and spinal cords from other waste material.

In addition we have 8 rendering companies and 17 animal food processors. These businesses will have to assure that the products that they produce are free of brain and spinal cord as well. Clarification from FDA is needed on what type of assurance is necessary and who is responsible for the assurance.

Depending on how it is implemented, the rule may make pick up of dead animals cost prohibitive for producers, which could threaten the environment and, potentially, public health. Farmers would need to bury dead animals or bring them to a landfill that would accept the animals. Any animal disease outbreak would cause landfills not to accept any dead animals due to public concern. Further, the estimated cost of bringing a dead animal to landfill is \$22.50 per 1000 lbs. Other options, such as incinerators and digesters, are expensive and not widely available. Without any type of market for their dead stock, producers will be inclined to put them aside and let them decompose, presenting other public health and environmental issues.

There would be little economic incentive for rendering companies to deal with dead animals. Right now dead animal collectors and renderers charge farmers approximately \$50.00 to pick up dead animals on the farm. Projected costs under the proposed rules would be to charge at least \$85.00 per animal to cover the pick up cost, cost of removal of SRM's, and costs of disposal.

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Rendered product is made up of approximately one-third fat, while the remaining rendered product is made up of other non fat product. What is going to be done with the non fat portion? It could be used as fertilizer, although there may be concerns about the fertilizer spreading the BSE prion.

The new rule would impose other potential problems on renderers and others, such as:

- Assurances from customers that SRM material would actually be removed. If the assurances aren't provided no pick up service would be given to customers.
- The need for separate pick up vehicles to handle SRM material.
- Available space at rendering companies to conduct sorting of raw products.
- It's unclear under the rule whether it would require meat establishments to have separate barrels and possibly a separate room for storage and removal of SRM's. We would appreciate clarification on this matter from FDA.

If the rule is enacted, increased inspections oversight would be necessary to ensure compliance to ensure the prohibited material is being removed, especially with regard to custom slaughter and other animal processors not inspected by USDA or equivalent authorities. It is very difficult to remove spinal cords out of dead animals, especially in the winter time when the carcasses are frozen. However, the rule does not appear to include additional resources for more inspectors. While this is a federal regulation, most compliance inspections fall to state personnel.

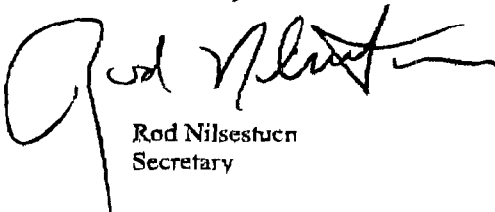
Another potential compliance issue involves the lack of specific record keeping requirements under the FDA rule proposal. Record keeping will be the main focus of inspections, but no new record keeping requirements were given by FDA. It is extremely difficult to test feed for illegal materials for a variety of reasons. FDA would avoid future risks by clarifying feed industry requirements concerning separation and segregation of product under the new rule.

Generally, any FDA rule change should:

- Promote harmonization with other countries' rules and regulations, particularly our border neighbors. It makes little sense to put our domestic feed and livestock industries in an unfair economic position by overburdening them with regulations while our trading partners play by different sets of rules.
- Be backed up by sound science. With all the regulatory safeguards implemented up to this point, the actual public health risk from a domestic BSE case is extremely low. It's important that our policies reflect this fact as our agencies work in partnership to maintain faith in the safety of American meat products, both domestically and internationally.

We thank you for the opportunity to make these comments and will appreciate your thoughtful consideration of them.

Sincerely,



Rod Nilsestuen
Secretary